Phathom Pharmaceuticals Announces Completion of Patient Enrollment in Pivotal Phase 3 Erosive Esophagitis Trial

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Topline results expected in second half of 2021

FLORHAM PARK, N.J., Nov. 30, 2020 (GLOBE NEWSWIRE) -- Phathom Pharmaceuticals, Inc. (Nasdaq: PHAT), a late clinical-stage biopharmaceutical company focused on developing and commercializing novel treatments for gastrointestinal diseases, today announced that it has completed patient enrollment in PHALCON-EE, the Company's pivotal Phase 3 clinical trial of vonoprazan for both the healing and maintenance of healing of erosive esophagitis (EE) as well as the relief of heartburn. Phathom exceeded the patient enrollment target of 1,000 patients. Phathom continues to expect topline results from the PHALCON-EE trial in the second half of 2021.

PHALCON-EE is a randomized, double-blind, two-phase, multicenter Phase 3 trial that has enrolled over 1,000 patients with EE in the U.S. and Europe. The first phase of the trial is evaluating the efficacy and safety of vonoprazan 20 mg administered once-daily (QD) compared to lansoprazole 30 mg QD for the healing of EE for up to eight weeks. The second phase of the trial is evaluating the efficacy and safety of vonoprazan 10 mg QD and 20 mg QD compared to lansoprazole 15 mg QD for the maintenance of healing of EE for 24 weeks. Both phases will also evaluate relief of heartburn symptoms.

"Completing patient enrollment in PHALCON-EE is a significant milestone for Phathom in our mission to bring innovative treatments to the millions of people battling gastrointestinal diseases. Exceeding our enrollment targets and timelines in the midst of a global pandemic underscores the great unmet need existing for new treatment options for patients with erosive esophagitis and further supports our belief that vonoprazan has the potential to transform the EE treatment paradigm," said Azmi Nabulsi, M.D., Phathom's Chief Operating Officer. "We are thankful for the unwavering commitment, support, and enthusiasm of the investigators and clinicians involved in executing this trial and are incredibly grateful to the patients who volunteered to participate in PHALCON-EE. We eagerly look forward to topline results from this trial in the second half of next year."

PHALCON-EE is one of two Phase 3 trials evaluating vonoprazan in gastrointestinal diseases. The second trial, PHALCON-HP, is a randomized, multicenter trial evaluating vonoprazan in combination with antibiotics for the successful eradication of *H. pylori* infection. Phathom expects to complete patient enrollment in PHALCON-HP in the first quarter of 2021 with topline results expected in the second quarter of 2021.

About Vonoprazan
Vonoprazan is an oral small molecule potassium-competitive acid blocker (P-CAB). P-CABs are a novel class of medicines that block acid secretion in the stomach. Vonoprazan has shown the potential to have rapid, potent, and durable anti-secretory effects as a single agent in the treatment of gastroesophageal reflux disease (GERD) and in combination with antibiotics for the treatment of Helicobacter pylori (*H. pylori)* infection. The U.S. Food and Drug Administration (FDA) has designated as a qualified infectious disease product (QIDP) and awarded Fast Track status to vonoprazan for the treatment of *H. pylori* infection in combination with both amoxicillin and clarithromycin and with amoxicillin alone. Phathom in-licensed the U.S., European, and Canadian rights to vonoprazan from Takeda, which completed 19 Phase 3 trials for vonoprazan and received marketing approval in 13 countries in Asia and Latin America.

About PHALCON-EE
PHALCON-EE is a randomized, double-blind, two-phase, multicenter Phase 3 trial that is planned to enroll approximately 1,000 patients with erosive esophagitis (EE) in the U.S. and Europe. The first phase of the trial is evaluating the efficacy and safety of vonoprazan 20 mg administered once-daily (QD) compared to lansoprazole 30 mg QD for the healing of EE for up to eight weeks. The second phase of the trial is evaluating the efficacy and safety of vonoprazan 10 mg QD and 20 mg QD compared to lansoprazole 15 mg QD for the maintenance of healing of EE for 24 weeks. Both phases are also evaluating heartburn symptoms.

About Phathom
Phathom Pharmaceuticals is a biopharmaceutical company focused on the development and commercialization of novel treatments for gastrointestinal diseases and disorders. Phathom has in-licensed the exclusive rights in the United States, Europe, and Canada to vonoprazan, a novel potassium competitive acid blocker (P-CAB) in late-stage development for the treatment of acid-related disorders. For more information about Phathom, visit the Company's website at www.phathompharma.com or follow the Company on social media: LinkedIn at www.linkedin.com/company/phathompharma and Twitter @PhathomPharma.

Forward Looking Statements
Phathom cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements

are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding when the Company expects to achieve targeted enrollment of patients in its PHALCON-HP Phase 3 clinical trial; the expected availability of topline results from the PHALCON-EE and PHALCON-HP Phase 3 clinical trials; and the potential to receive regulatory and exclusivity benefits as a result of QIDP and Fast Track designations. The inclusion of forward-looking statements should not be regarded as a representation by Phathom that any of its plans will be achieved. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Phathom's business, including, without limitation: the rate of patient enrollment in PHALCON-HP due to the COVID-19 pandemic is highly uncertain due to factors outside Phathom's control; potential additional delays in the commencement, enrollment and completion of clinical trials; patients already enrolled in PHALCON-EE and PHALCON-HP may not complete the clinical trials or public health conditions and governmental restrictions may lead Phathom to stopping such trials all together, which may adversely impact its trial results and development plans; Phathom's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of vonoprazan that may limit its development, regulatory approval and/or commercialization, or may result in recalls or product liability claims; QIDP and Fast Track designations may not actually lead to a faster development or regulatory review or extended exclusivity, and would not assure FDA approval of vonoprazan; Phathom's ability to obtain and maintain intellectual property protection for vonoprazan; Phathom's ability to comply with its license agreement with Takeda; Phathom's ability to maintain undisrupted business operations due to the ongoing spread of the COVID-19 coronavirus, including delaying or otherwise disrupting its clinical trials, manufacturing and supply chain, and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's Annual Report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Phathom undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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